

K120341

APR 27 2012

PREMARKET NOTIFICATION

510(k) Summary

Titanium Fletcher-Style Applicator Set

As required by 21 CFR 807.92

Submitter's Name:
(Paragraph (a) (1))

Varian Medical Systems
3100 Hansen Way, m/s E110
Palo Alto CA94304

Contact Name: Vy Tran
Phone: 650/424.5731
Fax: 650/842.5040
Date: 07 October 2011

Proprietary Name:
(Paragraph (a) (2))

GM11006200 Titanium Fletcher-Style Applicator Set-Defined
Geometry

Classification Name:
(Paragraph (a) (2))

Remote controlled radionuclide applicator system
21CFR892.5700
Class II

Common/Usual Name:
(Paragraph (a) (2))

GM11006200 Titanium Fletcher-Style Applicator Set

Predicate Devices:
(Paragraph (a) (3))

K980590Henschke Type GYN Applicator Set

Device Description:
(Paragraph (a) (4))

The GM11006200 Titanium Fletcher-Style Applicator Sets are designed for intracavitary radiotherapy treatments in the uterus, cervix, endometrium and vagina. They are compatible with Varian afterloaders and can be used in combination with the appropriate accessories.

The devices are intended to be used by trained and qualified personnel such as Radiation Oncologists, Physicians, Radiologists, Dosimetrists, Medical Physicists, and Nurses/MTRAs/Radiology Technicians/Radiographers in a hospital environment.

Intended Use:
(Paragraph (a) (5))

The Fletcher Style Applicator Sets (defined geometry) are intended to treat cancer of the uterus, cervix, endometrium and vagina

Technological Characteristics of the device compared with the predicate device:
(Paragraph (a) (6))

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	CLEARED DEVICE FEATURE/SPECIFICATION	NEW DEVICE
Predicate Device Clearance Number:	Henschke Type GYN Applicator Set K980590	N/A
Compatible Afterloader	VariSource	GammaMedplus GammaMed 12i(t) VariSource
Intended use	The Varian VariSource Remote High Dose Rate Afterloader (system including applicators and accessories) is a device intended to be used by trained and licensed medical personnel to provide radiation brachytherapy. The VariSource Henschke Type GYN applicator which is the subject of this 510(k) is a component of the VariSource system.	The GammaMed Titanium Fletcher-style Applicator Set with defined geometry was developed to treat cancer of the uterus, cervix, endometrium and vagina.
Indications for Use	The Henschke Type Applicator is indicated for use in any case where High Dose Rate (HDR) radiation treatment of the cervix and uterus is accepted clinical practice.	The GammaMed Titanium Fletcher-style Applicator Set with defined geometry was developed to treat cancer of the uterus, cervix, endometrium and vagina.
Design	Rigid intra-uterine tandem and a pair of interlocking colpostats with Henschke type ovoids. The hemispherical ovoids are segmented and will accept either tungsten or plastic inserts so that shielding is optional. Distance between ovoids is adjustable. Three tandems are provided: one straight and two with a minimum and maximum curvature of the distal end to accommodate intrauterine tilt.	Intrauterine Probe with stopper 30°, length: 40mm, 60mm, 80mm (optional 30mm, 50mm, 70mm) Colpostats: 20mm, 25mm, 30mm spread
Materials	Stainless Steel, Polysulphone, Tungsten	PEEK Titanium, stainless steel, PPSU.
Packing	individual	individual
Sterility	Provided Non sterile	Provided Non sterile
Sterilization method	EtO Gas sterilization or Steam sterilization	Steam sterilization

Sterilization conditions	30minutes \pm 2 minutes at 250°F \pm 5°F (121°C \pm 1°C).	15minutes @121°C 5 minutes @134°C 18 minutes @134°C
Biocompatibility	Biocompatibility not mentioned.	Full biocompatibility
Anatomical sites	uterus, cervix,	uterus, cervix, endometrium, vagina
Compatibility with the environment and other devices	Not stated to be CT compatible or MR Conditional for 3 Tesla	CT compatible MR Conditional for 3 Tesla
Rectal Retractor	Rectal Retractor not included as optional accessory	Rectal Retractor included as optional accessory

Non Clinical Tests (Paragraph (b) (1))

Biocompatibility tests were selected by reference to ISO 10933-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation & Testing* and 510(k) Memorandum - #G95-1 Initial Evaluation Tests for Consideration. The over- all results for the materials were as follows:

1. Released no leachable cytotoxic materials
2. Caused no reactions identified as sensitization
3. Showed no irritant/corrosive effect
4. Requirements of BS EN ISO 10993-1:2003 Biological evaluation of Medical Devices Part 1 and FDA#G95-1 have been met

Sterilization and Shelf Life tests have been undertaken on components that are representative of the Titanium Fletcher-style Applicator. The first group of tests was to verify that the proposed cleaning, disinfection and sterilization cycles were effective. The second was to verify the suitability of the design and material of the applicator components by inspecting for damage that might affect safety or effectiveness caused by the proposed number of cycles. In both types of test, components from other applicators that were representative of the components in the GM11006200 were used.

Other Bench Testing was performed to demonstrate that the device, functions correctly with both VariSource and GammaMedplus afterloaders; that the device can withstand the number of cycles of use that it will endure in its lifetime; that materials used are not significantly affected by the radiation they meet in the lifetime of the product; that the positional accuracy is adequate. The effects of Magnetic Resonance Imaging on the device when in patent contact were assessed. Usability was assessed to the requirements of IEC 62366:2007.

Clinical Tests (Paragraph (b) (2))

No Clinical Tests have been included in this pre-market submission

Conclusions (Paragraph (b) (2))

All the tests that were performed met the applied pass criteria. Varian considers the device to be safe and effective and to perform as well or better than the predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vy Tran
Vice President, Regulatory Affairs and Quality Systems
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304

APR 27 2012

Re: K120341
Trade/Device Name: Interstitial Plastic Needles
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: January 20, 2012
Received: February 3, 2012

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

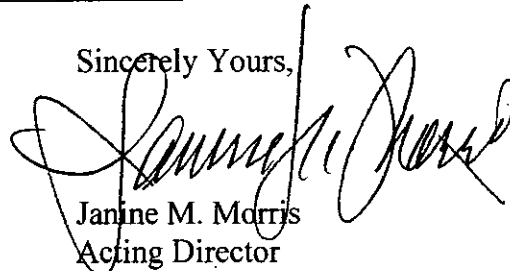
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K120341

Device Name: **Interstitial Plastic Needles**

Indications for Use:

The Interstitial Plastic Needles are designed for interstitial brachytherapy treatments in areas such as the head and neck, gynecological, breast and prostate.

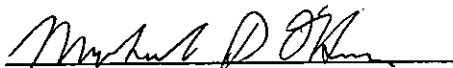
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120341